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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,341	10/13/2000	Hisakazu Kurita	K0448/7003	5123

7590 06/18/2003

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EXAMINER
GHALI, ISIS A D

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/673,341	Applicant(s) KURITA ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The receipt is acknowledged of applicants' request for extension of time, request under 1.114, and preliminary amendment C, all filed 04/01/2003.

Claims 1-12 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/01/2002 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 4,740,374 ('374) and US 5,866,157 ('157), each by itself or in combination with US 5,271,946 ('946).

US '374 teaches an adhesive composition for percutaneous absorption comprising alkaline salt of the drug (basic salt) and organic acid such as acetic acid. The amount of the drug salt is from 1 to 40 % and the amount of the organic acid is from 10 to 50 % (abstract; col.2, lines 30-33; col.3, lines 67-68; col.4, lines 1-4, 57, 62; col.9, lines 12-15).

US '157 teaches an adhesive composition for matrix patch formulation comprising from 0.1 to 20 % (w/w) of a basic drug and from 0.01 to 15 % (w/w) of organic acid or its salt such as sodium acetate (abstract; col.2, lines 40-60; col.3, lines 9-25, 55-58; examples).

However, US '374 and US '157 do not disclose the organic acid in the powder from or the mean diameter of the powder particles.

US '946 teaches a pharmaceutical composition comprising sodium acetate having a particle size of about 0.1 to 200 micrometer used for as oral and topical composition in an amount of 5-70 % (col.3, lines 10-33; col.4, lines 38-41; col.6, lines 58-62). The dosage form of the composition include plaster (col.3, line 24). The composition comprising the sodium acetate having this particle size provides controlled release of the active substance (abstract).

Thus, it would have been obvious to one having ordinary skill in the art at he time of the invention to provide percutaneous composition comprising a base drug salt and an organic acid salt as disclosed by any of US '347 and US '157, and replace the organic acid salt by sodium acetate as disclosed by US '946, motivated by the teaching of US '947 that the composition comprising the sodium acetate having this particle size provides controlled release of the active substance, with reasonable expectation of having a controlled release percutaneous composition.

Response to Arguments

5. Applicant's arguments filed 04/01/2003 have been fully considered but they are not persuasive.

Applicants' arguments:

- The main gist of applicants' argument to the above rejection is that none of the cited prior art teaches that the organic acid salt in the form of powder or the specific mean diameter that improves the skin permeability of the drug.
- The cited prior art does not teach percutaneous absorption preparations.
- No motivation to combine the teachings of US '374 or US '157 with US '946.

Examiner's position:

- Both of US '374 and US '157 disclose the combination of base drug and organic acid salt in an adhesive preparation, as claimed by the applicants. The references are silent regarding the state of sodium acetate, and that does not exclude its presence as a powder. Sodium acetate is a known as powder; see the "Condensed Medial Dictionary", page 1007, 1008. Applicants failed to show superior and unexpected results that show criticality in the claimed particle sizes. Both references teach that the presence of sodium acetate in the preparation for the same purpose desired by applicants, that is improved percutaneous absorption, see US '374, col.4, lines 47-50, and US '157, col.2, lines 32-39. It is within the skill in the art to determine the diameter of the particle in order to achieve a beneficial effect.
- Each of the cited references teaches percutaneous preparation; see US'374 abstract and col.2, lines 30-31; US 157 col.2, lines 23-29; US '946 col.3, line 24.
- US '946 is relied upon for the solely teaching of the size of the sodium acetate particles and its use in topical and oral pharmaceutical compositions. US '946

teaches that the composition comprising the sodium acetate having this particle size provides controlled release of the active substance. Thus, it would have been obvious to one having ordinary skill in the art to provide a composition comprising a base drug and an organic acid salt in the form of a powder and select the particle size of the powder that required to achieve the desired rate of permeation across the skin, with reasonable expectation of having a controlled release percutaneous composition.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)305-1235.

Isis Ghali
Examiner
Art Unit 1615

Isis Ghali